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Development and validation of a new mealtime assessment tool (MAT) for patients with dysphagia: A cross sectional study

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Abstract

Purpose. This study aimed to create a new quantitative and qualitative Mealtime Assessment Tool (MAT) to be administered by the not institutional caregiver to explore the dysphagic patient's mealtime behavior.

Methods. The development and validation process consisted of three steps: firstly, identification of items for the questionnaire, then pilot testing phase of the first version of the instrument and finally a psychometric evaluation in which the test was administered to the target population (adult inpatients with diagnosed and undiagnosed oropharyngeal dysphagia).

Results. A factorial analysis explained 51% of the variance and grouped the 12 items of the scale into three categories that defined: a) structural setting and compliance at mealtime, b) behavioral attitude at mealtime, c) structural setting as a function of possible distractibility. The concurrent validity using the *Dysphagia Outcome Severity Scale* and *Three Oz Water Swallow Test*, as the gold standard, was $r = 0.01$. Cronbach's alpha was 0.709. Stability test-retest reliability had ICC values of 0.980 $p = 0.01$. The ROC curve using as state variable the De Pippo test as a dichotomous variable showed the under-curve area as 0.830 (95% CI, 0.763 to 0.897).

Conclusions. The validation process led to the conclusion that the MAT is a valid, reliable and stable scale for caregivers. *Clin Ter* 2020; 171 (4):e??-??. doi: 10.7417/CT.2020.????

Key words: caregiver, dysphagia, elderly, oropharyngeal dysphagia, screening tool, swallowing disorder

Introduction

Dysphagia, as every impediment or difficulty of bolus progression's on swallowing function, in addition to being neurogenic, iatrogenic, myopathic, metabolic and structural, can also present with difficulties linked to pathophysiology; it can be secondary to underlying diseases.

Wirth et al. (1) report that Oropharyngeal dysphagia (OD) is recognized as one of the clinical conditions of highest-prevalence (15%) in inpatients over 65 years. It increases up to 51% in institutionalized elderly patients, and

this often leads to severe complications that go unrecognized, undiagnosed and untreated. Elderly patients are often unaware that they are having difficulty swallowing (2).

The rehabilitation of dysphagia involves several stages. The assistance of a speech therapist can help in the recovery of the individual by providing speech training. Depending on the severity of the problem, this can enable the patient to recover a physiological or functional level of swallowing (3). Valuable information can be collected from the mealtime setting, which has the potential to provide knowledge essential to treatment and ultimately to the patient's discharge. This mealtime information can expose other factors that require attention. It is not always possible for a speech therapist to be present during mealtimes, but treatment will involve all people engaged in the patient's support, including healthcare professionals, family members and caregivers (4).

The more the rehabilitation process is able to support and enable normal physiological functioning, the quicker and safer will be the restoration of a function that, in addition to its being vital, has strong social value. Providing adequate training for family members and caregivers involves a reduction of risks and the ability to recover a key moment of satisfaction. An adequate swallowing function is limited to "functional swallowing" (as opposed to "physiological" swallowing). Within the rehabilitation program, this involves postural as well as dietary benefits (5).

The rationale for the development of the new scale was to address the limitations of previous questionnaires, as many studies dwell more on nutritional or nursing factors, with their related scales, or else approach dysphagia purely in terms of speech therapy (6). The main aim of this study was to develop and validate a questionnaire for exploring a patient's behavior at mealtimes, which can be administered by the dysphagia patient's caregiver.

Methods

The present study was conducted by health professionals of Sapienza University of Rome and ROMA – Rehabilitation

& Outcome Measures Assessment Association. (7-17) The authors employed a combination of methods for the development and validation of the Mealtime Assessment Tool (MAT). The development and validation process consisted of three phases.

The first phase involved the identification of items for the questionnaire. The second phase involved the pilot testing of the first version of the instrument. The final phase involved administering it to the target population, adult inpatients with diagnosed and undiagnosed oropharyngeal dysphagia, followed by a psychometric evaluation of the results.

The sample for the study included both professionals and caregivers involved with inpatients aged between 23 and 96 years, who had been diagnosed with dysphagia secondary to various neurological disorders, or whose dysphagia was undiagnosed. The sample size involved 140 patient caregivers. The subjects who participated in the study were recruited at the "San Giovanni Battista" Hospital in Rome and at the "Villa Fulvia" Nursing Home in Rome between April 1, 2016 and December 30, 2016. The administration of the scale was not conducted with subjects of pediatric age, for whom the questions would need to be reformulated in relation to their age.

The first and second phase: identification of items for the questionnaire, pilot testing. The authors performed a review of the literature searching papers and questionnaires related to mealtime approaches to dysphagia. PubMed was consulted and research on dysphagia or swallowing disorder published between 1986 and 2016 was searched for the following search terms were utilized: "swallowing disorder" "caregiving" "Oropharyngeal dysphagia" "mealtime" AND "care" AND "scale" AND "tool" AND "screening" AND "elderly" AND "outcome" AND "nurse". The search was limited to English and Italian. The types of paper selected were those describing instruments that measure the quality of care provided in relation to the rehabilitation of dysphagia.

The MAT scale was performed with "Griglia di osservazione del paziente disfagico durante il pasto", which has already been published as a qualitative grid, and an abridged version of this was used. The first instrument was developed as a qualitative grid only and consisted of two parts: an observation of the patient and a checklist. The original grid was longer (with 46 items) and the qualitative instrument was administered by a speech-therapist (18). This grid was designed only for patients monitoring during the meal but not for quantitative purposes. Authors decided to create a tool suitable for administration by a caregiver for quantitative measuring the inherent situation at mealtimes to be used in the completion of a broader assessment carried out by a speech-therapist. In the first phase, a new scale was developed to obtain quantitative information from a participant during a mealtime. The reason was to allow a more objective evaluation of the swallowing ability of the patient. This was done in addition to a clinical and methodological evaluation or screening, which can quickly identify swallowing behavior. The first version of the scale consisted of a pool of 46 potential items. Ten expert speech-therapists were asked to classify the items into three categories: structural investigation, patient compliance with postural and dietary requirements, and swallowing skills. Ambiguous items that could not be clearly classified into

one of these dimensions were excluded by the experts. At this stage, a total of 30 items were eliminated because have been considered redundant and incurable with respect to the functional features that should be represented. Finally, the items were modified according to recommendations by the caregivers, and then the first draft of the MAT (with 16 items) was administered to a sample of 5 caregivers. Four of these have been considered too technical in writing to be cared for by a caregiver, for example, "Does the patient keep the posture of the anterophytic head?"

Third phase: Psychometric testing. The third phase involved a group of eight experts: a speech pathologist, a neurologist, a psychiatrist, a geriatrician, a physiotherapist, and three speech therapists. The trial proceeded in two steps: the first step aimed to investigate the validity of the content and to ensure that the items included in the MAT scale were in fact able to evaluate a patient's behavior during a meal given by the caregiver. Each of the experts involved indicated whether the questions were relevant for each of the three domains on a scale from five to one (from the best performance to the worst). The judgments on each question were then evaluated on a dichotomous scale (as relevant / irrelevant) and then the proportion of experts who judged the items as significant was calculated (to give the content validity of each item). Furthermore, the proportion of items was calculated according to the various scales as judged by all the experts (to give the entire MAT content validity). This step ended when the experts involved had reached complete agreement on the importance of each specific item in the whole test. The aims of this phase were to evaluate the quality of the items generated and to eliminate those proving to be inadequate. This study, therefore, through the application of the proposed scale to a small number of caregivers, aimed to assess the validity (of policy and content), and reliability (test-retest reliability and internal consistency) and to ensure that technical vocabulary, negative wordings, and double negatives were avoided. The final version of the questionnaire was reduced to 12 items.

Thus the second step of this stage included administration to population in order to assess psychometric properties of the tool. The validation study included the caregivers of patients' drawn from the admission lists of the hospitals who had been admitted over a period of six months. The MAT scale was used as an additional evaluation tool to allow the clinician to identify, more specifically, situations of risk related to dysphagia during a patient's mealtime. This is potentially also beneficial for patients without such a diagnosis, to provide information for those who provide medical care related to their daily needs.

Instruments. The MAT scale was designed with 3 sections. The first section asks respondents to describe the patient's demographic characteristics, including age, gender, primary pathology, weight and height. In addition, a speech-therapist must insert the patient's score on the Dysphagia Outcome Severity Scale (DOSS) (19) scale and the De Pippo (20) test a dichotomous variable, both taken as the gold standard.(21) The DOSS was adopted to investigate the severity of dysphagia. It provides, through the execution of a clinical budget of the patient, assigning a score from 1 (severe dysphagia), to 7 (swallowing the norm). The clinical and temporal criteria vary from patient to patient, from

condition to condition. The team finally weekly discuss the patient's clinical status, by nutrition's evaluation (oral, through SNG or PEG), any changes in the diet and performing further investigations. The score of 1 and 2 includes a aliment oral interpretation impossible or insufficient. The 3-4-5 levels provide the possibility of oral nutrition with diet modification and assistance. Levels 6-7 pre-they see a chance to oral feeding without any modification of the with-resistances with a single variant in level 6 are included physiological compensation of the subject.

De Pippo - Three Oz Water Swallow Test (20). The test consists of making the patient drink a certain volume of water while the examiner observes any choking, cough, change of voice or effort in swallowing. Run mode with a maximum dose of 90 ml H₂O - sensitivity 80% - 86% specificity. It 'a simple, inexpensive test, generally well accepted by the person. If positive is considered a strong predictor of potential also silent laryngeal aspiration, especially if combined with the measurement with pulseoximeter. The second section asks the respondent to complete the 12 items of the questionnaire: The first ten questions are answered on 5-point Likert-type scale where 1 denotes "never" and 5 denotes "often". In this way, "5", corresponds to the best performance and "1", to the worst performance. This type of response format minimizes the possibility of obtaining irrelevant answers. Time to fill in the questionnaire is about 10 minutes.

The 12 items concern in some situations that may help to define:

1. the patient's proper participation. The question is to investigate the participation of the subject being examined, referring, more specifically, to its degree of attention and vigilance at the time of the meal.
2. posture during the meal. A proper postural fit in the feeding phase is crucial: apart from the case of a specific positioning suggested by healthcare professionals experienced in dysphagia management, generally, the best posture is the session where the patient has to be sitting straight with a comfortable support for the forearms and feet resting on the ground. But if this position can not be taken, it is necessary to place it in bed, with the trunk raised as far as possible, even using more than one cushion to put as a back support. Misguided posture may adversely affect the swallowing mechanism - possibly already compromised - exposing the patient to increased risk of penetration and / or aspiration.
3. the presence or not of possible distractors. The functional ability to feed autonomously provides important insights into the motor skills of the patient in question.
4. the person's autonomy. The purpose of this question is to detect the presence or absence of distracting elements at the time of the meal. The patient must pay attention and focus on the correct way of taking food and swallowing, practicing any suggestions suggested by healthcare professionals experienced in dysphagia management, avoiding any source of distraction. Therefore, it is recommended that the environment where the meal is consumed should be well lit, quiet and silent.
5. the hydration. Proper maintenance of the body hydration level can no longer benefit a patient whose problems of swallowing may result in malnutrition, thereby affecting

his / her health. Drinking during meal is important but in the presence of food residue within the oral cavity, if the patient has not demonstrated adequate respiratory protection, it is recommended that you never use liquids to dispense the food.

6. the taste and appetite of the patient. The fact that the patient can or does not consume the daily meals entirely allows the clinician to understand if any problems can lead to difficulties in the oral administration of food that, if extended, leads the patient to fatigue: it is important to suspend the meal to the first signs of collapse. In this case, do not overlook the sensory component of taste: it is well known that taste is of utmost importance in patients with swallowing disorders, as rapid stimulation of sensory receptors favors the speed of the oral phase.
7. the focus on the activity that is taking place. The way we use oral organs for swallowing and phoning is different because different neuronal mechanisms are at the base of their implementation: in fact, in this case, we speak of 'function dissociation'. It is important that the patient does not speak during the meal, since the act of speaking involves the activation of a series of anatomic-functional mechanisms that interfere with the maintenance of food within the oral cavity, exposing the patient to a high risk of penetration and suction.
8. the presence of cough. Cough is an important defense mechanism for swallowing, in case of inhaled episodes. Evaluation of voluntary cough and refractory cough should be evaluated: in subjects with cortical lesions, there may be no voluntary cough but there is a valid reflective mechanism. Conversely, in some instances of cranial nerve injury, there may be voluntary cough but absent the reflex mechanism due to sensory deficiency. The presence of cough is an indispensable element to be evaluated during swallowing tests because it allows the clinician, first of all, to decide on the type of diet that the patient needs to follow. In addition, if instrumental observation is not possible, the type of cough put into effect allows to understand what happens at that level and to make inferences: the strength of cough depends on the vital lung capacity, the adequacy glottic occlusion and contraction strength of abdominal muscles.
9. the possible change of voice before and after the meal. Verifying that there is a change in voice after a swallowing act, provides relevant information about possible penetration / aspirations in laryngeal aditus.
10. 11. the presence of residues at the level of lips or tongue. The presence of residues inside and outside of the oral cavity can be a sign of the difficulty of buccal and lingual prassie.
12. and nostrils after chewing. The last item, however, is indicative of the feather-veil function.

The third section asks the respondents to describe some qualitative parameters regarding specific items. The second page of the questionnaire, provides some elaborations and explanations how the questions are to be completed. For example:

In relation to question 2, you must specify how the patient is positioned during the mealtime. For example, if the patient is sitting, is it 1) in a wheelchair, 2) on a chair or 3) on the bed? Knowing what the postural alignment of the patient is

during the process of feeding, is critical to an understanding of any related swallowing disorders. It is stressed that the best posture during a meal enables the neck of the subject to correspond to an angle of approximately 90°. This is especially relevant in the case of any swallowing disorders already diagnosed (22).

In relation to question 5, the fluid intake mode (whether thickened or not) favored by the patient must be identified. This may be 1) a filler can, 2) a cup, 3) a spoon, 4) a tube or 5) a bottle. Each alternative corresponds to a different level of difficulty for the patient with a swallowing disorder (23). The use of a straw, for example, facilitates the intake of liquids, but causes air to be swallowed, which is difficult for older patients, particularly for those with specific respiratory problems (24). The use of a bottle of water, however, implies hyperextension of the neck that would increase the speed of the passage. At the same time, this would reduce the time when the upper esophageal sphincter was open, providing a high risk for the inhalation of the fluid.

With reference to question 8, the caregiver is required to specify which foods make the patient cough in order to investigate a possible correlation between the dysphagia and specific textures. The respondent will complete the questionnaire on two distinct occasions. The first assessment will take place on the day of the patient's admission and the second one, four days later.

Ethical consideration. The study complied with all the principles of the Helsinki Declaration. A participant information sheet providing details of the study accompanied the questionnaire. Patients were informed that their participation in the study was strictly on a voluntary basis and in the event that they wished to withdraw from the study, there would be no consequences in relation to their treatment, hospitalization and care (25,26).

Data Analysis. The study was undertaken in two neuro-rehabilitation hospitals in Italy. Cronbach's alpha was used to quantify the internal reliability of the total questionnaire. Content validity was addressed through the process employed to develop the instrument. The process included basing the items on the prior instrument. Stability (test-retest) reliability was determined with Pearson's correlation coefficient between the first time (time 1=test) and the second (time 2= retest) responses to the scale's test. Concurrent validity was performed through Pearson's correlation coefficient and was also determined with Spearman's and Kendall's correlation coefficients on the two scales considered the gold standard for the evaluation of oropharyngeal dysphagia: the DOSS scale (21) and the De Pippo - Three Oz Water Swallow Test (20). The first of these is an internationally recognized test and the second is a screening test which is valid in Italy. In the absence of validated tests that evaluate the same dimensions as the MAT scale, aspects of speech therapy evaluation were used to construct the validity, which was performed by using factor analysis, a statistical method that allows you to identify the different item clusters sufficiently to justify their presence. In order to test the sensitivity and specificity of the scale, we carried out an analysis of the ROC curve by choosing the De Pippo test calculated as a dichotomous variable as the state variable. Statistical analyses were performed using the SPSS 23.0 statistical software.

Results

The final version of the scale is available as Appendix 1. The study was carried out with a sample of 175 caregivers of patients with diagnosed and undiagnosed dysphagia. In total, 25 of the sample were not included because they did not conform to the selection criteria. The validation test was therefore done by the caregivers of 150 patients aged between 23 and 96 years. Ten were tested during the initial phase only and 140 did the test-retest. The average age was 70.64±16.8 years, and 55% were female and 45% male. All had different primary diseases. The weight and height measurements of the sample were recorded in order to calculate their BMI (see Table 1).

Content validity. The validation process was conducted for the contents of the MAT scale. This involved a group of eight experts with the following skills: a speech pathologist, a neurologist, a physiatrist, a geriatrician, a physiotherapist and three speech therapists. In the process of investigating the content validity of the items included in the MAT scale, these experts were able to evaluate a patient's behavior during a meal given by the caregivers. Each of the experts involved indicated whether the questions could be deemed relevant to each of the three domains, on a scale of five to one (from best performance to worst). The judgments on each question were then grouped according to a dichotomous scale (as relevant or irrelevant). It was then calculated what proportion of experts had judged each item as relevant (the content validity of each item) to give the proportion of the scale judged relevant by all the experts (or the entire MAT content validity). This phase ended when the experts involved reached total agreement on the importance of each specific item in the entire test (Appendix 1)

Concurrent validity. The concurrent validity was performed by analyzing correlations with the two tools considered to be the gold standard for the assessment of Oropharyngeal dysphagia: the DOSS Scale and the De Pippo -Three Oz Water Swallow Test. The first of these is an internationally recognized method and the second, a screening test that is validated in Italy. An analysis of the correlations between the MAT scale and the two gold standard scales revealed a broad significant correlation with both gold standards. In

Table 1. Demographic characteristics of the patients at the baseline

	Sample=140
Age (mean±SD)	70.64±16.87
Gender men n°(%)	63 (45)
Body Mass Index (mean±SD)	23.91±4.52
Disease n°(%)	
Cerebrovascular	49 (35)
Brain injury	13 (9.3)
Neurodegenerative	8 (5.7)
Orthopedic	63 (45)
Others	7 (5)

Table 2. Item Analysis for Total of Items

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
ITEM1	45.74	30.886	0.449	0.410	0.679
ITEM2	45.54	32.192	0.281	0.227	0.697
ITEM3	45.71	34.105	0.035	0.104	0.730
ITEM4	46.46	25.027	0.618	0.583	0.636
ITEM5	46.54	28.020	0.397	0.379	0.682
ITEM6	46.44	33.069	0.113	0.194	0.721
ITEM7	46.25	32.520	0.124	0.081	0.724
ITEM8	46.19	30.383	0.353	0.228	0.688
ITEM9	45.80	30.291	0.497	0.401	0.672
ITEM 10	46.14	28.368	0.543	0.539	0.659
ITEM 11	46.14	28.224	0.630	0.580	0.650
ITEM 12	45.31	34.562	0.154	0.076	0.709

particular, there was a significant direct correlation between the MAT scale and the DOSS ($r=0.512$ $p=0.01$), with the De Pippo test correlation on $r = -0.537$ $p = 0.01$.

Reliability. The Internal consistency (IC) test of the MAT scale was performed on the data obtained before the first administration in order to determine the size of the sample (see Table 2). It was calculated that $N=140$ subjects were needed to ensure the internal consistency of each item. The alpha reliability of the scale as a whole was found to be equal to 0.709, or a sufficient value to ensure the IC 0.709 was the same, with a value for ICC =0.631- 0.775. To see if the test itself would provide the same results after repeated assessments by the same operator, the test-retest reliability was conducted to estimate the stability of individual measures over time, after which we calculated the intraclass correlation coefficient (ICC) between the two assessments by Pearson's r (see Table 3). The scale was stable from a statistical point of view regarding the ICC values 0.980 $p=0.01$. By the same operator, the intraclass correlation coefficient was calculated as (ICC) 0.990 $p=0.01$.

Construct validity. There is a lack of tests that evaluate the same dimensions as the MAT, as most studies dwell more on nutritional or nursing factors with related scales (27) or on aspects that apply only to speech therapy assessment. (6) For this reason, construct validity was performed by using factor analysis, a statistical method that allows you to locate the different clusters of items distinctly enough to justify their separate existence. Factor analysis explains the reason why the variance of the scale was 51% and it

found a strong correlation between the items grouped into the three main areas: a) structural setting and compliance with respect to the activity (items 1, 4, 5, 9, 10, 11 & 12); b) behavioral attitude to mealtime (items 2 & 6); c) structural setting as a function of possible distractibility (items 3, 7 & 8). In relation to construct validity, structural setting and compliance in relation to the activity (items 1, 4, 5, 9, 10, 11 & 12) gave valuable information on the feeding mode, and the function of structural aspects (5). Voice changes after swallowing inform us of possible penetrations / aditus laryngeal aspirations as well as the presence of residues in the mouth that may indicate difficulties of praxis lingual (27). It known that taste is of extreme importance in the case of patients with swallowing disorders, as the fast stimulation of sensory receptors is most conducive to the speed of the oral phase. These items showed strong correlation. Finally, the last three items give functional information related to possible structural problems. Behavioral structure (items 2 and 6) explore the postural structure of the person during the meal: the importance of having the neck at 90° during swallowing for subjects with disorders is an integral part of postural allowance, and is also an important nutritional factor for the person. The structural setting as a function of possible distractibility (items 3, 7 & 8) explore the patient's attention to the activity being carried out, in addition to the presence of distracting factors in the environment (TV, tablet, mobile phone etc.). Coughing after swallowing informs us of possible penetrations / aditus laryngeal aspirations (28) as well as the presence of residues inside the nostrils that

Table 3. Test-retest reliability - Inter-rater analysis- (N=140)

ITEM	TEST Mean \pm S.D.	RETEST Mean \pm S.D.	ICC	ICC 95%	p Value
1	4.47 \pm 0.85	4.47 \pm 0.83	0.936	(911-954)	0.01
2	4.66 \pm 0.83	4.68 \pm 0.81	0.979	(939-997)	0.01
3	4.49 \pm 1	4.55 \pm 0.92	0.919	(845-982)	0.01
4	3.74 \pm 1.39	3.79 \pm 1.36	0.987	(981-990)	0.01
5	3.66 \pm 1.35	3.7 \pm 1.36	0.973	(962-981)	0.01
6	3.76 \pm 1.04	3.84 \pm 1.02	0.959	(943-971)	0.01
7	3.96 \pm 1.16	3.97 \pm 1.14	0.960	(945-972)	0.01
8	4.02 \pm 1.04	4.09 \pm 0.99	0.940	(917-957)	0.01
9	4.41 \pm 0.83	4.46 \pm 0.83	0.966	(952-975)	0.01
10	4.06 \pm 1.05	4.11 \pm 1.06	0.972	(961-980)	0.01
11	4.06 \pm 0.95	4.13 \pm 0.97	0.955	(937-967)	0.01
12	4.89 \pm 0.43	4.93 \pm 0.33	0.847	(786-890)	0.01

can be indicative of a lack of pharyngeal functionality (29) (see table 4).

Sensitivity and Specificity. In order to test the sensitivity and specificity of the scale, we carried out the analysis of the ROC curve by choosing the De Pippo test, calculated as a dichotomous variable, as the state variable (see Figure1). The under-curve area was 0.830 (95% CI, 0.763 to 0.897). The results obtained show a sensitivity of 98% and a specificity of 90% where a pathology cut-off would correspond to a score of 39.00.

Discussion

The dysphagia in inpatients has been the focus of much interest in the recent scientific literature. (30-32) To assess dysphagia, a valid and reliable tool is needed that can be used worldwide.

The aim of this study was to evaluate the validity and reliability of the MAT scale, a dysphagia evaluation tool that can be administered by caregivers in the absence of a speech therapist. The validation of the scale was conducted by examining the content validity, the construct validity

Table 4. Factor analysis with Promax Rotation

Component	1	2	3
Does the patient participate actively in the meal?	0.598	-0.359	0.356
During the meal the patient is sitting?	0.403	-0.434	0.506
During the meal, does your TV, computer, tablet go off?	0.032	0.526	0.504
Is the patient autonomous in taking food?	0.812	-0.136	-0.175
Does the patient drink during the meal?	0.582	0.025	-0.416
Does the patient consume the whole meal?	0.158	-0.512	0.428
Does the patient eat in silence?	0.155	0.390	0.179
Does the patient eat without coughing?	0.433	0.500	0.301
Is the patient's voice equal before and after the meal?	0.627	0.407	0.134
After chewing the patient's lips are cleaned of food residue?	0.742	-0.043	-0.304
After chewing the patient's tongue is cleaned by food residue?	0.792	0.027	-0.181
After chewing the patient's nostrils are cleaned of food residue?	0.259	0.109	0.042
Variance	28.28	12.15	10.76

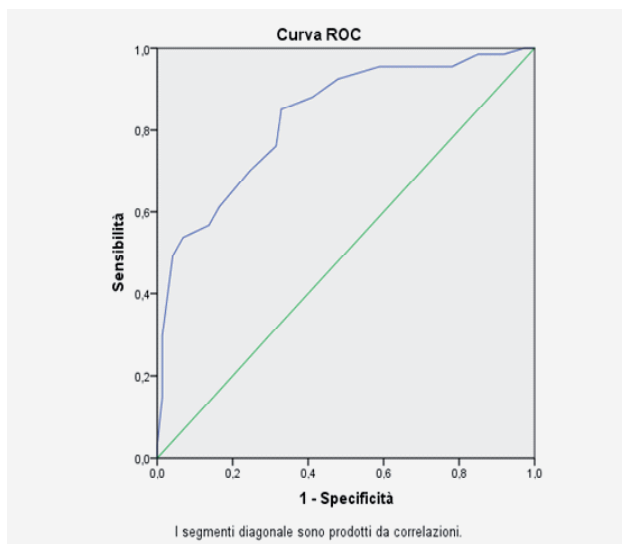


Fig. 1. The ROC curve- Diagnostic quality

and the reliability. The process of establishing the content validity led to the final protocol of the test.

The analysis of its concurrent validity in relation to the De Pippo and DOSS tests has highlighted the significant correlation between them and demonstrated that the scale is valid for diagnosing the presence/absence of dysphagia. In particular, an analysis of the results found a significant correlation between the values on the DOSS scale and the responses to certain questions (4, 10 & 11) as provided by operators who filled out the scale. The De Pippo test (20) is, however, closely associated with other items (8 & 9): in case of negativity or positivity, the scores of these questions were found to be, respectively, higher or lower.

In relation to the reliability of the scale, the analysis of internal consistency showed a Cronbach Alpha value sufficient to ensure the consistency and cohesion between the items, according to the guideline (33).

From an analysis of the ROC curve, the scale was also found to be sensitive and specific when highlighting a threshold value able to discriminate the presence of pathology. In reference to the sensitivity of the scale, it is important to emphasize the weight of the diseased patient and their age, as these factors represented further significant findings in this investigation. The pathologies represented in the sample were grouped, mainly as either cerebrovascular or orthopedic. In most cases, the swallowing disorder had already been diagnosed and the information collected from the completion of the questionnaire served to confirm the diagnosis, showing a significant correlation between the test answers and the respective retests. Moreover, the most interesting finding, was that some of the patients for whom there was a diagnosis of dysphagia, when, in spite of answers to questions, it was confirmed that a difficulty was present, this was not a condition linked to their disease but rather to the age of the subject.

The purpose of the scale is to have a follow-up of the behavior of the patients with discomfort followed in their hospital and extra-hospital rehabilitation path. For this rea-

son it was conceived for non-institutional caregivers and was tested on the latter (dedicated family or caregivers).

Degenerative function changes in the different ages of life and in the senescence, there are often changes in the swallowing structures that in association with other factors (sarcopenia, xerostomy) can contribute to the onset of presbyphagia. This tool could also be used to detect possible swallowing problems within the elderly population since the rise in the mean age of life will contribute to the increase of frail elderly patients with comorbidities with other pathologies, to prevent abnormal pneumonia and reduce the cost of healthcare. (1,26)

Limitations. Although this study was successful in developing a new tool for caregivers and this instrument was validated, the results show some limitations. The internal consistency is not strong but with stratification by simplicity it becomes significantly greater. Moreover, this first validation was carried out only with inpatients, future studies should consider other settings. The instrument was developed and validated in Italy and therefore its cultural origins and influences need to be acknowledged before applying it in other cultural settings. Overcoming this problem would increase the instrument's transferability to other populations and cultural backgrounds where the caregiver situation may not be the same and the process of translation, cultural adaptation and re-validation would need to be implemented. Finally, when analyzing the possible limitations of our study, while the majority of the scale variance is explained, factor analysis and the reduction of related components highlighted the poor correlation of some items in comparison with others.

Conclusions

This study develops, in a context in which the interest in the rating scales is growing, (34-37) the first scale for assessing the dysphagic patient's mealtime behavior that can be administered by the not institutional caregiver. The validation process has led to the conclusion that the MAT scale is valid, reliable and stable. It may be considered a handy guide for non-professionals to work with. The data obtained is consistent with studies reported in the literature that discuss the management of oropharyngeal dysphagia in adults, with particular attention to the evaluation of meal times as part of the rehabilitation project involving the caregivers' cooperation (38,39). We hope to expand the work with future investigations into the correlation with other validated tools (40).

COMPETING INTERESTS. The authors declare that there are no competing interests regarding the publication of this paper.

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Griglia di osservazione al pasto del paziente con disfagia (G.O.P.)
 AMITRANO A. - ROSSI G.

Cod.	Età:	Sesso: M <input type="checkbox"/> F <input type="checkbox"/>	Eziologia:	esordio	durata	P	H	BMI	DOSS	De Pippo
L'operatore che compila la scala:										P.TOT

1. Durante il pasto, il paziente partecipa attivamente?
 Sempre Quasi sempre A volte Quasi mai Mai NV
2. Durante il pasto il paziente è seduto?
 Sempre Quasi sempre A volte Quasi mai Mai NV
3. Durante il pasto il computer, tablet, televisore sono spenti?
 Sempre Quasi sempre A volte Quasi mai Mai NV
4. Il paziente è autonomo nell'assunzione del cibo?
 Sempre Quasi sempre A volte Quasi mai Mai NV
5. Il paziente beve durante il pasto?
 Sempre Quasi sempre A volte Quasi mai Mai NV
6. Il paziente consuma interamente le pietanze?
 Sempre Quasi sempre A volte Quasi mai Mai NV
7. Il paziente mangia in silenzio?
 Sempre Quasi sempre A volte Quasi mai Mai NV
8. Il paziente mangia senza tossire?
 Sempre Quasi sempre A volte Quasi mai Mai NV
9. La voce del paziente è uguale prima e dopo il pasto?
 Sempre Quasi sempre A volte Quasi mai Mai NV
10. Dopo la masticazione, le labbra del paziente sono pulite da residui di cibo?
 Sempre Quasi sempre A volte Quasi mai Mai NV
11. Dopo la masticazione, la lingua è pulita da residui di cibo?
 Sempre Quasi sempre A volte Quasi mai Mai NV
12. Dopo la masticazione, le natiche del paziente sono pulite da residui di cibo?
 Sempre Quasi sempre A volte Quasi mai Mai NV

Pasto completato in minuti: (INDICARE IL TEMPO totale) punteggio:

In una scala da 1 a 10 come valuteresti la seguente scala?

1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	----

Osservatore

In riferimento alla domanda n° 1 specificare se:

Il paziente è seduto:

- | | | |
|----|---------------|--------------------------|
| 1. | in carrozzina | <input type="checkbox"/> |
| 2. | sulla sedia | <input type="checkbox"/> |
| 3. | sul letto | <input type="checkbox"/> |

In riferimento alla domanda n° 5 specificare se:

Il paziente **beve** con:

- | | | |
|----|------------|--------------------------|
| 1. | bicchiere | <input type="checkbox"/> |
| 2. | tazza | <input type="checkbox"/> |
| 3. | cucchiaino | <input type="checkbox"/> |
| 4. | cannuccia | <input type="checkbox"/> |
| 5. | battiglia | <input type="checkbox"/> |

In riferimento alla domanda n° 8 specificare con quali cibi **tossisce** il paziente:
